

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SANDRA WHITE	:	CIVIL ACTION
	:	
v.	:	
	:	NO. 16-2638
MEDTRONIC, INC., et al.	:	

MEMORANDUM

Bartle, J.

August 31, 2016

Plaintiff Sandra White on behalf of her son Jordan White (Jordan) filed this diversity action on May 27, 2016 against defendants Medtronic, Inc. and related companies¹ to recover damages suffered by Jordan as a result of the malfunction of medical devices designed, manufactured, and sold by defendants. The defendants have now moved to dismiss the complaint for failure to state a claim on the ground of federal preemption under Rule 12(b)(6) of the Federal Rules of Civil Procedure. They also raise the bar of the statute of limitations as to some claims and assert that the pleading requirements of Ashcroft v. Iqbal, 556 U.S. 662 (2009) and Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007) have not been met.

1. These related companies are: Medtronic Neuromodulation, a division of Medtronic, Inc.; Medtronic Puerto Rico Operations, Inc.; and Medtronic Logistics, LLC.

For purposes of a motion under Rule 12(b)(6), we must construe all well-pleaded facts in favor of the plaintiff. See Umland v. Planco Fin. Servs., Inc., 542 F.3d 59, 64 (3d Cir. 2008). The court may also consider exhibits attached to the complaint, matters of public record and authentic documents on which the complaint is based when attached to a motion to dismiss. Pension Benefits Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993).

According to the complaint, Jordan suffers from cerebral palsy. On February 5, 2010, he had implanted in his abdomen a pump known as a SynchroMed® II Device and an Intrathecal Catheter intended to deliver a programmed amount of baclofen medication into his spine. They were manufactured and sold by defendants. The expected benefit was the reduction or elimination of Jordan's need for oral medication. Thereafter, the efficacy of the SynchroMed® II Device began to wane, and Jordan experienced increased muscle tightness, rigidity and pains. The catheter was found to have an occlusion. It was removed and a new catheter was inserted on August 1, 2012. Again, the device began to fail, causing Jordan to suffer various physical complications. On May 29, 2014, this second catheter and the SynchroMed® II Device were surgically removed as the catheter had fractured.

In 1976, Congress enacted the Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360c et seq., to the Federal Food, Drug, and Cosmetic Act ("FDCA") 21 U.S.C. §§ 301 et seq. The MDA brought medical devices under federal regulation and oversight. Under the MDA regime, those devices involved in this lawsuit are assigned to Class III. 21 U.S.C. § 360c(a)(1). They may not be sold without premarket approval by the Food and Drug Administration ("FDA") and are subject to continuing reporting requirements, including reporting of incidents when a device has caused death or serious injury or malfunction in a manner likely to cause or contribute to death and serious injury. See id.

On April 29, 2015, Judge Joan N. Ericksen of the United States District Court for the District of Minnesota entered a Consent Decree of Permanent Injunction prohibiting Medtronic from manufacturing and distributing SynchroMed® Implantable Infusion Pumps in violation of the terms of the Decree. United States v. Medtronic, Inc., No. 15-2168 (D. Minn. Apr. 29, 2015) (order entering injunction and consent decree). Plaintiff maintains that defendants are selling SynchroMed® II Device in violation of the Decree.

The complaint contains eight claims for relief:

(1) Manufacturing Defect; (2) Failure to Warn; (3) Negligence;

(4) Negligence per se; (5) Breach of Express Warranty;

(6) Breach of Implied Warranty; (7) Negligent Misrepresentation; and (8) Violation of Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), 73 P.S. §§ 201-1 et seq. The defendants argue that all claims are preempted by the MDA.

The preemption clause of the MDA provides:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue to effect with respect to a device intended for human use any requirement -

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Supreme Court in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), analyzed the issue of preemption under § 360k(a) of the MDA. It explained that a court must first determine if the FDA has requirements for the device in question. Id. at 321. If it does, the court must then decide if the state law claims are based on requirements different from or in addition to federal requirements. Id. at 321-22. Preemption exists when the answer to both inquiries is in the affirmative.

The Riegel plaintiff, alleging that he had suffered serious and permanent injuries as a result of a defective

catheter, filed a complaint containing claims under New York common law. Id. at 320. The District Court held that the claims of strict liability, breach of implied warranty, and negligence in the design testing, inspection, distribution, labeling, marketing, and sale of the catheter were preempted. Id. at 320-21. It further ruled as preempted plaintiff's negligent manufacturing claim insofar as it was not predicated on a violation of federal law. Id. at 321. While the District Court allowed plaintiff's express warranty and negligent manufacturing claims based in violation of federal law to go forward, it ultimately granted summary judgment in favor of Medtronic. Id. at 321 n.2. The Court of Appeals and the Supreme Court affirmed. The Supreme Court made clear that claims alleging violation of "state tort law notwithstanding compliance with the relevant federal requirements" cannot stand. Id. at 330. The Court explained:

State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. § 360k(a)(1). Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements.

Id.

Our Court of Appeals had previously considered preemption under § 360k(a) in Michael v. Shiley, 46 F.3d 1316 (3d Cir. 1995). There, plaintiff brought suit under Pennsylvania law for a defective heart valve. The Court held that state law negligence, strict liability, and breach of implied warranties claims were preempted but allowed a claim for breach of an express warranty to proceed. Id. at 1336. Such warranties, it reasoned, "arise from the representations of the parties which are made the basis of the bargain and do not result from the independent operation of state law." Id. at 1325. They are not in the words of § 360k, "a requirement" under state law. Id. at 1328. Finally, the Third Circuit held that claims of fraud on the FDA were preempted but fraud on surgeons and cardiologists was not.² Id. at 1329-31; see also Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001).

It is undisputed that the devices in question were subject to and received premarket approval by the FDA. Based on the Supreme Court's decision in Riegel and the Third Circuit's decision in Michael, the claims in the pending complaint for failure to warn, negligence, negligence per se, breach of implied warranty, and negligent misrepresentation are preempted under § 360k(a) and must be dismissed. The claims with a

2. Since plaintiff here does not raise a fraud claim, we do not have to decide whether Michael's allowance of such a claim conflicts with the Supreme Court's later decision in Riegel.

negligence component as well as the breach of implied warranty claim all allege duties or impose requirements on defendants that are different from or in addition to the federal requirements. See 21 U.S.C. § 360k(a)(1). The essence of the failure to warn claim is the failure to warn users and purchasers of the dangers of the device in issue. Plaintiff has pointed to no federal law or regulations requiring such warnings. To the extent that defendants failed to warn the FDA of the dangers, there is simply no parallel state law duty imposed on manufacturers and sellers to report to a federal agency.

The claim of manufacturing defects in violation of federal law and regulations may proceed since the state law claim simply parallels the federal violations. See Riegel, 552 U.S. at 330. This claim does not seek to enforce any requirements other than those found in the MDA and relevant regulations. The claim of breach of express warranty is not preempted by § 360k(a) because such warranty is not a requirement of state law.

There remains the claim under the UTPCPL, 73 Pa. Stat. and Cons. Stat. Ann. §§ 201-1, et seq. This Pennsylvania statute provides a private cause of action for "any person who purchases or leases goods or services primarily for personal, family or household purposes and thereby suffers any

ascertainable loss of money or property, real or personal" when the loss occurs as a result of "unfair or deceptive acts or practices in the conduct of any trade or commerce" Id.

§§ 201-3, 201-9.2(a). Since a manufacturer of a medical device has no duty to disclose information to a consumer such as plaintiff, such a consumer has no cause of action under the statute. McLaughlin v. Bayer Corp., 2016 WL 1161578 at *18 (E.D. Pa. Mar. 22, 2016); Kee v. Zimmer, 871 F. Supp. 2d 405, 411 (E.D. Pa. 2012). Thus, we need not reach the issue of preemption.

Defendants also argue that the plaintiff's claims concerning the first catheter, which was implanted on February 5, 2010 and removed on August 1, 2012, are barred by the statute of limitations. Under Pennsylvania law, personal injury claims are untimely if the action is brought more than two years after the occurrence at issue. 42 Pa. Stat. and Cons. Stat. Ann. § 5524(2) & (7). The pending lawsuit was not filed until May 27, 2016.

Plaintiff, however, relies on the discovery rule which tolls the running of the statute of limitations until the "plaintiff knows, or reasonably should know: (1) that he has been injured, and (2) that his injury has been caused by another party's conduct." Debiec v. Cabot Corp., 352 F.3d 117, 128-29 (3d Cir. 2003); see also Gleason v. Borough of Moosic, 15 A.3d

479, 485 (Pa. 2011). Plaintiff maintains that Jordan did not know or have reason to know of Medtronic's violation of law until the injunction was entered against it in 2015. The resolution of this issue cannot be decided on a motion to dismiss and will have to await discovery.

Defendants also contend that the breach of express warranty claim with respect to SynchroMed® II Device and the first catheter is barred by the applicable Pennsylvania four-year statute of limitations. See 42 Pa. Stat. and Cons. Ann. § 5525(a); 13 Pa. Stat. and Cons. Stat. Ann. § 2725(a). For a breach of warranty claim, the cause of action accrues when "tender of delivery is made." 13 Stat. and Cons. Stat. Ann. § 2725(b). This is so "regardless of the aggrieved party's lack of knowledge of the breach." Id. Thus, no discovery rule applies in this instance. See O'Brien v. Eli Lilly & Co., 668 F.2d 704, 711 (3d Cir. 1981); Floyd v. Brown & Williamson Tobacco Co., 159 F. Supp. 2d 823, 831 (E.D. Pa. 2001). The plaintiff's claim for breach of express warranty with respect to the SynchroMed® II Device and the first catheter, which as noted above were implanted on February 5, 2010, is untimely since the action was not filed for over six years, that is not until May 27, 2016. This part of that breach of express warranty claim will be dismissed. See Robinson v. Johnson, 313 F.3d 128, 135 (3d Cir. 2002).

Finally, defendants argue that the complaint fails to meet the pleading requirements of Iqbal, 556 U.S. at 678 and Twombly, 550 U.S. at 544, 570. To the extent claims remain, we are not persuaded. The complaint satisfies the plausibility standard set forth in those cases.